

## BABY PETROLEUM JELLY- white petrolatum cream

Rejoice International Inc.

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

### Baby Petroleum Jelly

#### Active Ingredients

#### Purpose

White Petroleum 99.9% ..... skin protectant

#### Uses

temporarily protects and helps relieve chapped or cracked skin and lips

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

XtraCare

100% Pure Petroleum Jelly

Baby Fresh Scent

#### Directions

- change and cleanse diaper area, and allow to dry
- apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged

#### Warnings

##### For external use only

**When using this product** do not get into eyes

**See a doctor** if condition lasts more than 7 days

##### Do not use on

- deep puncture wounds
- animal bites
- serious burns

**Inactive ingredients** fragrance



Drug Facts		Drug Facts (continued)
<b>Active ingredients</b>	<b>Purpose</b>	<b>Directions</b> ■ change and cleanse diaper area, and allow to dry ■ apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged
White Petroleum 99.9%..skin protectant		<b>Inactive ingredients</b> fragrance.
<b>Use</b> helps prevent diaper rash		<b>QUESTIONS/COMMENTS?</b> 1-855-345-5575
<b>Warnings</b>		<b>DISTRIBUTED BY:</b>
For external use only		REJOICE INTERNATIONAL, INC
When using this product do not get into eyes		NORTHVILLE, MI 48168 U.S.A.
<b>See a doctor</b> if condition worsens or lasts more than 7 days		<b>MADE IN INDIA</b>
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away		8 49607 09201 4



Drug Facts		Drug Facts (continued)
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b>	<b>Directions</b> ■ change and cleanse diaper area, and allow to dry ■ apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged
<b>Use</b> helps prevent diaper rash		<b>Inactive ingredients</b> fragrance.
<b>Warnings</b> For external use only When using this product do not get into eyes		<b>QUESTIONS/COMMENTS?</b> 1-855-345-5575
<b>See a doctor</b> if condition worsens or lasts more than 7 days		<b>DISTRIBUTED BY:</b> REJOICE INTERNATIONAL, INC NORTHVILLE, MI 48168 U.S.A. MADE IN INDIA
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away		8 49607 09204 5



Drug Facts		Drug Facts (continued)
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b>	<b>Directions</b> ■ change and cleanse diaper area, and allow to dry ■ apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged
<b>Use</b> helps prevent diaper rash		<b>Inactive ingredients</b> fragrance.
<b>Warnings</b> For external use only When using this product do not get into eyes		<b>QUESTIONS/COMMENTS?</b> 1-855-345-5575
<b>See a doctor</b> if condition worsens or lasts more than 7 days		<b>DISTRIBUTED BY:</b> REJOICE INTERNATIONAL, INC NORTHVILLE, MI 48168 U.S.A. MADE IN INDIA
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away		8 49607 09207 6



Drug Facts		Drug Facts (continued)
<b>Active ingredients</b> White Petroleum 99.9%...skin protectant	<b>Purpose</b>	<b>Directions</b> ■ change and cleanse diaper area, and allow to dry ■ apply product as needed, with each diaper change, especially at bedtime and when exposure to wet diapers may be prolonged
<b>Use</b> helps prevent diaper rash		<b>Other information</b> store at room temperature
<b>Warnings</b> For external use only When using this product do not get into eyes		<b>Questions/Comments?</b> 1-855-345-5575
<b>See a doctor</b> if condition worsens or lasts more than 7 days		<b>Inactive ingredients</b> fragrance.
<b>Do not use on</b> ■ deep puncture wounds ■ animal bites ■ serious burns		<b>DISTRIBUTED BY:</b> REJOICE INTERNATIONAL, INC NORTHVILLE, MI 48168 U.S.A. MADE IN INDIA
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away		
		8 49607 109198 7

## BABY PETROLEUM JELLY

white petrolatum cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)			PETROLATUM	99 g in 100 g
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-076-01	113 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
2	NDC:57337-076-02	170 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
3	NDC:57337-076-03	227 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
4	NDC:57337-076-04	368 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		06/15/2015	

**Labeler** - Rejoice International Inc. (078741245)

Establishment			
Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(57337-076)

Revised: 9/2019

Rejoice International Inc.